

REALQUALITY  
► RQ-STI CT/NG/MG

3STI

One-tube Multiplex PCR

Kit for detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium* by Real-Time PCR.

Pathogen	Target Region
STI CT/NG/MG Real time mix	
<i>Chlamydia trachomatis</i>	<ul style="list-style-type: none"><li>MOMP gene</li><li>Cryptic plasmid</li></ul>
<i>Neisseria gonorrhoeae</i>	<ul style="list-style-type: none"><li>porA pseudo gene</li><li>multi-copy opa gene</li></ul>
<i>Mycoplasma genitalium</i>	<ul style="list-style-type: none"><li>MgPa gene</li></ul>

The kit includes the use of a double amplification target for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. This approach guarantees the maximum diagnostic reliability for the identification of variants and a high analytical sensitivity, since the cryptic plasmid of CT and the opa gene of NG are present in multiple copies (respectively from 7 to 10 copies per CT organism and up to 11 copies per NG organism).

PRODUCT CHARACTERISTICS:

- Detection and identification of 3 STI causing pathogens by one-tube multiplex PCR.
- Two target regions for both *C. trachomatis* and *N. gonorrhoeae* increase the clinical specificity and sensitivity of the test.
- Ready-to-use PCR mastermix, includes dUTP/UNG system to prevent carry over contamination.
- Internal control: amplification of  $\beta$ -globin gene in multiplex with pathogens genes.
- Positive controls included.
- Easy interpretation of results with AB Genius Report software.
- Validated instruments:

- AriaDx Real-Time PCR System (Agilent Technologies).
- Applied Biosystems 7500 Fast Dx Real-Time PCR System (Applied Biosystems).
- CFX96 Real-Time PCR Detection System (Bio-Rad).
- Rotor-Gene Q MDx (QIAGEN).

SPECIMENS:

- DNA extracted from cervico-vaginal, urogenital, urethral swabs and urine. It has also been tested on DNA extracted from prostatic secretion, rectal swab, seminal fluid and urethral biopsy.

SHELF LIFE:

- 18 months.

FLUOROPHORES:

Colour	Target
Green	<i>Chlamydia trachomatis</i> (CT)
Yellow	<i>Neisseria gonorrhoeae</i> (NG)
Red	<i>Mycoplasma genitalium</i> (MG)
Orange	$\beta$ -globin

ORDERING INFORMATION:

CODE	PRODUCT	FORMAT
RQ-107-4M/6M	REALQUALITY RQ-STI CT/NG/MG	50/100 test

This product uses technology patented by Biosearch Technologies, licensed for use in Human Molecular Diagnostic applications.



REALQUALITY  
► RQ-SevenSTI

7STI

Two-tubes Multiplex PCR

Kit for detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium*, *Mycoplasma hominis*, *Trichomonas vaginalis*, *Ureaplasma urealyticum* and *Ureaplasma parvum* by Real-Time PCR.

Pathogen	Target Region
STI CT/NG/MG Real time mix	
<i>Chlamydia trachomatis</i>	<ul style="list-style-type: none"><li>MOMP gene</li><li>Cryptic plasmid</li></ul>
<i>Neisseria gonorrhoeae</i>	<ul style="list-style-type: none"><li>porA pseudo gene</li><li>multi-copy opa gene</li></ul>
<i>Mycoplasma genitalium</i>	<ul style="list-style-type: none"><li>MgPa gene</li></ul>

The kit includes the use of a double amplification target for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. This approach guarantees the maximum diagnostic reliability for the identification of variants and a high analytical sensitivity, since the cryptic plasmid of CT and the opa gene of NG are present in multiple copies (respectively from 7 to 10 copies per CT organism and up to 11 copies per NG organism).

PRODUCT CHARACTERISTICS:

- Detection and identification of 7 STI causing pathogens by two-tube multiplex PCR.
- Two target regions for both *C. trachomatis* and *N. gonorrhoeae* increase the clinical specificity and sensitivity of the test.
- Ready-to-use PCR mastermix, includes dUTP/UNG system to prevent carry over contamination.
- Internal control: amplification of  $\beta$ -globin gene in multiplex with pathogens genes.
- Positive controls included.
- Easy interpretation of results with AB Genius Report software.
- Validated instruments:

- AriaDx Real-Time PCR System (Agilent Technologies).
- CFX96 Real-Time PCR Detection System (Bio-Rad).
- Rotor-Gene Q 6plex (QIAGEN).

SPECIMENS:

- DNA extracted from urogenital, cervical-vaginal and urethral swabs and urine.

SHELF LIFE:

- 18 months.

Pathogen	Target Region
STI TV/MH/UU/UP Real time mix	
<i>Trichomonas vaginalis</i>	<ul style="list-style-type: none"><li>Repeated sequence</li></ul>
<i>Mycoplasma hominis</i>	<ul style="list-style-type: none"><li>16s rRNA</li></ul>
<i>Ureaplasma urealyticum</i>	<ul style="list-style-type: none"><li>Urease gene</li></ul>
<i>Ureaplasma parvum</i>	<ul style="list-style-type: none"><li>Urease gene</li></ul>

FLUOROPHORES:

Reaction 1 (RX-1)	
Colour	Target
Green	<i>Chlamydia trachomatis</i> (CT)
Yellow	<i>Neisseria gonorrhoeae</i> (NG)
Red	<i>Mycoplasma genitalium</i> (MG)
Orange	$\beta$ -globin
Reaction 2 (RX-2)	
Colour	Target
Green	<i>Trichomonas vaginalis</i> (TV)
Yellow	<i>Ureaplasma urealyticum</i> (UU)
Red	<i>Mycoplasma hominis</i> (MH)
Orange	<i>Ureaplasma parvum</i> (UP)

ORDERING INFORMATION:

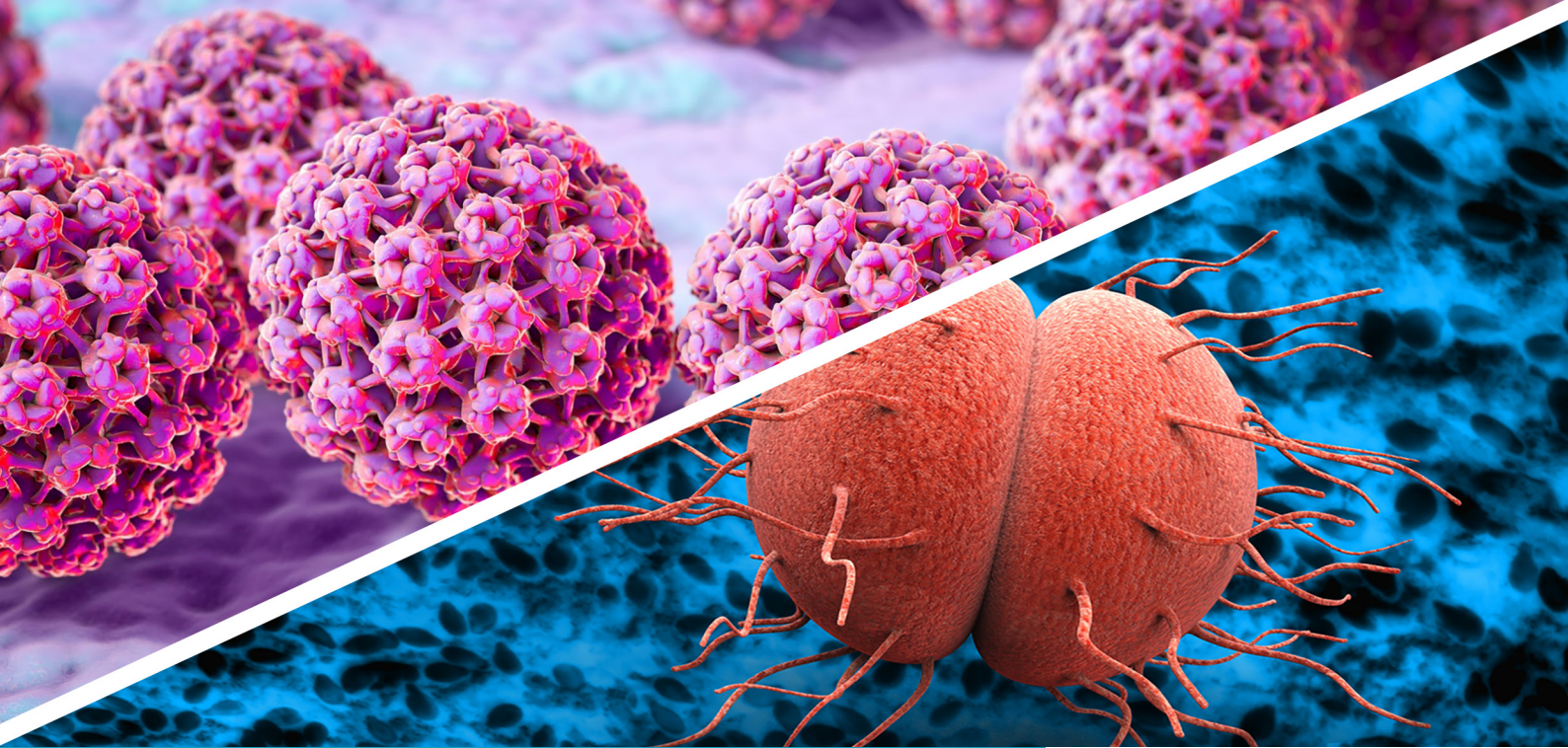
CODE	PRODUCT	FORMAT
RQ-127-4M/6M	REALQUALITY RQ-SevenSTI	50/100 test

This product uses technology patented by Biosearch Technologies, licensed for use in Human Molecular Diagnostic applications.



REALQUALITY  
Human Papilloma Virus (HPV)  
and other Sexually Transmitted  
Infections (STI)

REALQUALITY kits allow the fast detection of Human Papilloma Virus (HPV) and other pathogens causing Sexually Transmitted Infections (STI).



- Human Papilloma Virus (HPV)
- Chlamydia trachomatis* (CT)
- Neisseria gonorrhoeae* (NG)
- Mycoplasma genitalium* (MG)
- Mycoplasma hominis* (MH)
- Ureaplasma parvum* (UP)
- Ureaplasma urealyticum* (UU)
- Trichomonas vaginalis* (TV)

AB-BRO\_RQ-HPV-STI\_e2024-0322



REALQUALITY

- ▶ RQ-HPV HR Multiplex
- ▶ RQ-HPV Screen

Kits for detection and identification of high-risk genotypes of the *Human Papillomavirus* by Real-Time PCR (regions E6-E7).

REALQUALITY RQ-HPV HR Multiplex and RQ-HPV Screen have been developed according to the latest guidelines for HPV DNA assays for diagnostic screening. The assays detect the 14 high-risk HPV types and allow direct identification of the HPV genotypes 16 and 18. The assays use single-tube multiplexed PCR including an internal control. This guarantees ease of use and makes the assays suitable for high-throughput testing. To ensure maximum diagnostic reliability these kits target the E6 and E7 oncogenes. One of the key events of HPV-induced oncogenesis is integration of the HPV genome into the host genome, which may lead the loss of a portion of its sequence. However, the E6 and E7 genes have been found to remain unaffected. For this reason, the use of a diagnostic system that is based on the detection of the HPV E6 and E7 genes drastically reduces the risk of false-negative results owed to viral integration.

REALQUALITY RQ-HPV Screen is clinically validated according to Meijer guidelines (Iacobellis et al., 2018; Meijer C. et al., 2009).

PRODUCT CHARACTERISTICS:

- Amplified region: E6 and E7 genes.
- Genotyping: HPV 16 and 18.
- Detected high-risk genotypes: HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.
- Ready-to-use PCR mastermix, includes dUTP/UNG system to prevent carry over contamination.
- Internal control: Amplification of  $\beta$ -globin gene in multiplex with pathogen genes.
- Positive Controls included.
- Easy interpretation of results with AB Genius Report software.
- Validated instruments:  
[REALQUALITY RQ-HPV HR Multiplex](#)
  - Applied Biosystems 7500 Fast/Fast Dx Real-Time PCR System (Applied Biosystems).
  - CFX96 Real-Time PCR Detection System (Bio-Rad).
  - LightCycler® 480 Real-Time PCR System version II (Roche).  
[REALQUALITY RQ-HPV Screen](#)
  - Applied Biosystems 7500 Fast/Fast Dx Real-Time PCR System (Applied Biosystems).
  - AriaDx Real-Time PCR System (Agilent Technologies).

SPECIMENS:

- DNA extracted from cervical, vaginal, urethral, oral and anal swabs; from urethral, vaginal and foreskin biopsy tissue; and from vaginal secretion and FFPE samples.

SHELF LIFE:

- 18 months.

14HPV

One-tube Multiplex PCR

REALQUALITY

- ▶ RQ-HPV HR/LR Multiplex

Kit for detection and identification of high-risk and low-risk genotypes of the *Human Papillomavirus* by Real-Time PCR (regions E6-E7).

REALQUALITY RQ-HPV HR/LR is an IVD that allows exhaustive diagnostic analysis. Using only two multiplexed PCRs that include internal controls, the assay detects the 14 high-risk HPV types, the 6 HPV types that are classified by the IARC as possibly high-risk and the two most common low-risk HPV genotypes. In addition, the kit allows direct identification of the main causative agents for HPV-related cancer, the HPV genotypes 16 and 18, as well as HPV 6 and HPV 11, two low-risk HPV types of particular clinical interest. To ensure maximum diagnostic reliability these kits target the E6 and E7 oncogenes. One of the key events of HPV-induced oncogenesis is integration of the HPV genome into the host genome, which may lead the loss of a portion of its sequence. However, the E6 and E7 genes have been found to remain unaffected. For this reason, the use of a diagnostic system that is based on the detection of the HPV E6 and E7 genes drastically reduces the risk of false-negative results owed to viral integration.

PRODUCT CHARACTERISTICS:

- Amplified region: E6 and E7 genes.
- Genotyping: HPV 16, 18, 6 and 11.
- Detected high-risk genotypes: HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.
- Detected possibly high-risk genotypes: HPV 26, 53, 67, 70, 73, 82.
- Ready-to-use PCR mastermixes, include dUTP/UNG system to prevent carry over contamination.
- Internal control: Amplification of  $\beta$ -globin gene in multiplex with pathogen genes.
- Positive Controls included.
- Easy interpretation of results with AB Genius Report software.
- Validated instruments:
  - Applied Biosystems 7500 Fast/Fast Dx Real-Time PCR System (Applied Biosystems).
  - CFX96 Real-Time PCR Detection System (Bio-Rad).
  - LightCycler® 480 Real-Time PCR System version II (Roche).
  - Rotor-Gene Q MDx (QIAGEN).

SPECIMENS:

- DNA extracted from cervical, vaginal, urethral, oral and anal swabs; from urethral, vaginal and foreskin biopsy tissue; and from vaginal secretion and FFPE samples.

SHELF LIFE:

- 18 months.

22HPV

Two-tubes Multiplex PCR

FLUOROPHORES:

Reaction 1 (RX-1)	
Colour	Target
Yellow	HPV 16
Red	HPV 18
Green	HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68
Orange	$\beta$ -globin
Reaction 2 (RX-2)	
Colour	Target
Yellow	HPV 6
Red	HPV 11
Green	HPV 26, 53, 67, 70, 73, 82
Orange	$\beta$ -globin

ORDERING INFORMATION:

CODE	PRODUCT	FORMAT
RQ-99-4M/6M	REALQUALITY RQ-HPV HR/LR Multiplex	50/100 test
RQ-99R-4M/6M	REALQUALITY RQ-HPV HR/LR Multiplex (for LC480 II - Roche)	50/100 test

This product uses technology patented by Biosearch Technologies, licensed for use in Human Molecular Diagnostic applications.



REALQUALITY

- ▶ RQ-Multi HPV Detection

Kit for detection of 28 high-risk and low-risk genotypes of the *Human Papillomavirus* by Real-Time PCR (regions E6-E7).

REALQUALITY RQ-Multi HPV Detection is an IVD that allows exhaustive diagnostic analysis. Using only two multiplexed PCRs that include internal controls the assay detects 14 high-risk, 6 possibly high-risk and 8 low-risk HPV genotypes. In addition, the kit allows direct identification of the main causative agents for HPV-related cancer, the HPV genotypes 16 and 18. To ensure maximum diagnostic reliability these kits target the E6 and E7 oncogenes. One of the key events of HPV-induced oncogenesis is integration of the HPV genome into the host genome, which may lead the loss of a portion of its sequence. However, the E6 and E7 genes have been found to remain unaffected. For this reason, the use of a diagnostic system that is based on the detection of the HPV E6 and E7 genes drastically reduces the risk of false-negative results owed to viral integration.

PRODUCT CHARACTERISTICS:

- Amplified region: E6 and E7 genes.
- Genotyping: HPV 16 and 18.
- Detected high-risk genotypes: HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.
- Detected possibly high-risk genotypes: HPV 26, 53, 67, 70, 73, 82.
- Detected low-risk genotypes: HPV 6, 11, 40, 42, 43, 44, 55, 83.
- Ready-to-use PCR mastermixes, include dUTP/UNG system to prevent carry over contamination.
- Internal control: Amplification of  $\beta$ -globin gene in multiplex with pathogen genes.
- Positive Controls included.
- Easy interpretation of results with AB Genius Report software.
- Validated instruments:
  - Applied Biosystems 7500 Fast/Fast Dx Real-Time PCR System (Applied Biosystems).
  - CFX96 Real-Time PCR Detection System (Bio-Rad).
  - LightCycler® 480 Real-Time PCR System version II (Roche).

SPECIMENS:

- DNA extracted from cervical, vaginal, urethral, oral and anal swabs; from urethral, vaginal and foreskin biopsy tissue; and from vaginal secretion and FFPE samples.

SHELF LIFE:

- 18 months.

28HPV

Two-tubes Multiplex PCR

FLUOROPHORES:

Reaction 1 (RX-1)	
Colour	Target
Yellow	HPV 16
Red	HPV 18
Green	HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68
Orange	$\beta$ -globin
Reaction 2 (RX-2)	
Colour	Target
Yellow	HPV 40,42,43, 44, 55, 83
Red	HPV 6, 11
Green	HPV 26, 53, 67, 70, 73, 82
Orange	$\beta$ -globin

ORDERING INFORMATION:

CODE	PRODUCT	FORMAT
RQ-103-4M/6M	REALQUALITY RQ-Multi HPV Detection	50/100 test
RQ-103R-4M/6M	REALQUALITY RQ-Multi HPV Detection (for LC480 II - Roche)	50/100 test

This product uses technology patented by Biosearch Technologies, licensed for use in Human Molecular Diagnostic applications.

